REQUEST FOR QUOTATION TH				RFQ Lis	ĽΙ	S NOT A	SMALL B	USINES	SS SET-ASI	DE		GE 01	F PAGES
1. REQUEST NO. 2. DATE ISSUED RFQ-RT-03-00298 07/16/2003			ĒD	3. REQUISITION/PURCHASE REQUEST NO. PR-RT-03-00850			U	4. CERT. FOR NAT. DEF. UNDER BOSA REG. 2 AND/OR DMS REG. 1			ΓING		
5a. ISSUED BY US EPA Mail Drop: E105-0 OARM SERVICE CENTER					02	2			6. DELIVER BY (Date)				
				IONS DIVISION				C	9/01/2003				
	RESEARCH	TRIANGLE P	ARK, N	IC 27711				7. D	ELIVERY				
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	CLAUSEN			(919) 541-3002		Fax: (919)			9. DESTINATION				
- N			8.	то:					a. Name of Consignee US EPA Mail Drop: PHARMACOKINETICS BRANCH 8512				•
a. Name		•••		b. Company					b. Street Address				
c. Street Addı	ess							RES	RESEARCH TRIANGLE PARK				
								c. Ci	ty RTP				
d. City			e. St	e. State f. Zip Code				d. St	d. State NC e. Zip Code 27711				
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12 DISCOUNT	FOR PROMPT	DAVMENT	a.	10 Calendar Days	(%)	b.20 Calen	dar Days (%	(a) c.30	Calendar Days	(%)	d. Cale		
12. DISCOUNT FOR PROMPT PAYMENT NOTE: Additional provisions and representations X are lare										N	lumber	Pe	ercent
						attached.	F OF DEDG	ON AUTU	ODIZED TO	Īa:	E Dot- 0	* 0	station.
13. NAME AND ADDRESS OF QUOTER a. NAME OF QUOTER b. STREET ADDRESS						14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION 15. Date Of Quotation				nation			
						16. SIGNER							
c. COUNTY				a. NAME (Type or Print) b. TELEPHONE				ONE					
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		REQUEST FOR QUOTATION	IUN-				2
REQUEST NO. DATE ISSUED			REQUIS				
RFQ-RT-03-00298 07/16/2003			PR-RT-	03-00850			
ITEM NO. (a)		SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOU! (f)	NT
1 (continued)	award purposed by options to the to The Government munacceptable if tunbalanced. Evaluate Government to [c] A written not offer, mailed or successful offercespecified in the contract without Before the offer Government may acknowled the contract whether or not the options of the contract without services of the offer whether or not the options of the contract without services of the offer whether or not the options of the	e Government will evaluate offers for adding the total price for all btal price for the basic requirement. any determine that an offer is the option prices are significantly that any continuous shall not obligate of exercise the option(s). Stice of award or acceptance of any otherwise furnished to the for within the time for acceptance offer, shall result in a binding further action by either party. It is specified expiration time, the steep an offer (or part of an offer), were are negotiations after its a written notice of withdrawal is					

Additional Clause(s):

CUSTOM

N.C. SALES TAX EXEMPT

North Carolina General Statute 105-164.13(17) and Rule No. 48 Sales and Use Tax Regulations.

EPA Federal Tax Identification Number 520852695

EPAAR

1552.211-79 COMPLIANCE WITH EPA POLICIES FOR INFORMATION RESOURCES MANAGEMENT (OCT 00)

COMPLIANCE WITH EPA POLICIES FOR INFORMATION RESOURCES MANAGEMENT (OCT 2000)

- (a) Definition. Information Resources Management (IRM) is defined as any planning, budgeting, organizing, directing, training, promoting, controlling, and managing activities associated with the burden, collection, creation, use and dissemination of information. IRM includes both information itself, and the management of information and related resources such as personnel, equipment, funds, and technology. Examples of these services include but are not limited to the following:
- (1) The acquisition, creation, or modification of a computer program or automated data base for delivery to EPA or use by EPA or contractors operating EPA programs.
- (2) The analysis of requirements for, study of the feasibility of, evaluation of alternatives for, or design and development of a computer program or automated data base for use by EPA or contractors operating EPA programs.
- (3) Services that provide EPA personnel access to or use of computer or word processing equipment, software, or related services.
- (4) Services that provide EPA personnel access to or use of: Data communications; electronic messaging services or capabilities; electronic bulletin boards, or other forms of electronic information dissemination; electronic record-keeping; or any other automated information services.

EPAAR

1552.211-79 COMPLIANCE WITH EPA POLICIES FOR INFORMATION RESOURCES MANAGEMENT (II) (OCT 00)

- (b) General. The Contractor shall perform any IRM related work under this contract in accordance with the IRM policies, standards and procedures set forth in this clause and noted below. Upon receipt of a work request (i.e. delivery order or work assignment), the Contractor shall check this listing of directives (see paragraph (d) for electronic access). The applicable directives for performance of the work request are those in effect on the date of issuance of the work request.
- (1) IRM Policies, Standards and Procedures. The 2100 Series (2100-2199) of the Agencys Directive System contains the majority of the Agencys IRM policies, standards and procedures.
- (2) Groundwater Program IRM Requirement. A contractor performing any work related to collecting Groundwater data; or developing or enhancing data bases containing Groundwater quality data shall comply with EPA Order 7500.1A Minimum Set of Data Elements for Groundwater.

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1552.211-79 COMPLIANCE WITH EPA POLICIES FOR INFORMATION RESOURCES MANAGEMENT (III) (OCT 00)

- (3) EPA Computing and Telecommunications Services. The EnterpriseTechnology Services Division (ETSD) Operational Directives Manual contains procedural information about the operation of the Agencys computing and telecommunications services. Contractors performing work for the Agencys National Computer Center or those who are developing systems which will be operating on the Agencys national platforms must comply with procedures established in the Manual. This document may be found at: http://www.epa.gov/docs/etsdop/.
- (c) Printed Documents. Documents listed in (b)(1) and (b)(2) may be obtained from:

U.S. Environmental Protection Agency
Office of Administration
Facilities Management and Services Division
Distribution Section
Mail Code: 3204
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460 Phone: (202) 260-5797

(d) Electronic Access. A complete listing, including full text, of documents included in the 2100 Series of the Agencys Directive System is maintained on the EPA Public Access Server on the Internet at http://epa.gov/docs/irmpoli8/.

****end of clause****

FAR A

52.212-1 Instructions to Offerors-Commercial Items (OCT 00)

- (a) (1) North American Industry Classification System (NAICS) code and small business size standard. The NAICS code and small business size standard for this acquisition is 541690 "Other Scientific and Technical Consulting Services".
- (2) The small business size standard is <\$6M average annual revenue over the last three years.
- (3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.
- (b) Submission of offers. Submit signed and dated offers to the office specified in this solicitation at or before the exact time specified in this solicitation. Offers may be submitted on the Standard Form 18, letterhead stationery, or as otherwise specified in the solicitation. As a minimum, offers must show--

- (1) The solicitation number;
- (2) The time specified in the solicitation for receipt of offers;
- (3) The name, address, and telephone number of the offeror;
- (4) A technical description of the items being offered in sufficient detail to evaluate compliance with the requirements in the solicitation. This may include product literature, or other documents, if necessary;
- (5) Terms of any express warranty;
- (6) Price and any discount terms;
- (7) "Remit to" address, if different than mailing address;
- (8) A completed copy of the representations and certifications at FAR 52.212-3;
- (9) Acknowledgment of Solicitation Amendments;
- (10) Past performance information, when included as an evaluation factor, to include recent and relevant contracts for the same or similar items and other references (including contract numbers, points of contact with telephone numbers and other relevant information); and
- (11) If the offer is not submitted on the SF 1449, include a statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation. Offers that fail t

FAR B 52.212-1 Instructions to Offerors-Commercial Items (Continued 2) (OCT 00)

- (c) Period for acceptance of offers. The offeror agrees to hold the prices in its offer firm for 30 calendar days from the date specified for receipt of offers, unless another time period is specified in an addendum to the solicitation.
- (d) Product samples. When required by the solicitation, product samples shall be submitted at or prior to the time specified for receipt of offers. Unless otherwise specified in this solicitation, these samples shall be submitted at no expense to the Government, and returned at the sender's request and expense, unless they are destroyed during preaward testing.
- (e) Multiple offers. Offerors are encouraged to submit multiple offers presenting alternative terms and conditions or commercial items for satisfying the requirements of this solicitation. Each offer submitted will be evaluated separately.
- (f) Late submissions, modifications, revisions, and withdrawals of offers. (1) Offerors are responsible for submitting offers, and any modification, revisions, or withdrawals, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that offers or revisions are due.
- (2)(i) Any offer, modification, revision, or withdrawal of an offer received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not considered unless it is received before award is made, the Contracting Officer determines authorized representative if, before the exact time set for receipt of offers, the identity of the person requesting withdrawal is established and the person signs a receipt for the offer.

FAR C 52.212-1 Instructions to Offerors-Commercial Items (Continued 3) (OCT 00)

- (A) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of offers; or
- (B) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (C) If this solicitation is a request for proposals, it was the only proposal received.
- (ii) However, a late modification of an otherwise successful offer, that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (3) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the offer wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (4) If an emergency or unanticipated event interrupts normal Government processes so that offers cannot be received at the Government office designated for receipt of offers by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation or other notice of an extension of the closing date, the time specified for receipt of offers will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

FAR D 52.212-1 Instructions to Offerors-Commercial Items (Continued 4) (OCT 00)

(5) Offers may be withdrawn by written notice received at any time before the exact time set for receipt of offers. Oral offers in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile offers, offers may be withdrawn via facsimile received at any time before the exact time set for receipt of offers, subject to the conditions specified in the solicitation concerning facsimile offers. An offer may be withdrawn in person by an offeror or its authorized representative if, before the exact

time set for receipt of offers, the identity of the person requesting withdrawal is established and the person signs a receipt for the offer.

- (g) Contract award (not applicable to Invitation for Bids). The Government intends to evaluate offers and award a contract without discussions with offerors. Therefore, the offeror's initial offer should contain the offeror's best terms from a price and technical standpoint. However, the Government reserves the right to conduct discussions if later determined by the Contracting Officer to be necessary. The Government may reject any or all offers if such action is in the public interest; accept other than the lowest offer; and waive informalities and minor irregularities in offers received.
- (h) Multiple awards. The government may accept any item or group of items of an offer, unless the offeror qualifies the offer by specific limitations. Unless otherwise provided in the Schedule, offers may not be submitted for quantities less then those specified. The Government reserves less than those specified the Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit prices offered, unless the offeror specifies otherwise in the offer.

FAR E 52.212-1 Instructions to Offerors-Commercial Items (Continued 5) (OCT 00)

(i) Availability of requirements documents cited in the solicitation. (1)(i) The GSA Index of Federal Specifications, Standards and Commercial Item Description, FPMR Part 101-29, and Copies of specification, standa

GSAFederal Supply Service Specifications Section Suite 8100 470 East L'Enfant Plaza, SW Washington, DC 20407

Telephone (202) 619-8925 Facsimile (202) 619-8978.

- (ii) If the General Administration, Department of Agriculture, or Department of Veterans Affairs issued this solication, a single copy of specification, standards, and commercial item descriptions cited in this solicitation may be obtained free of charge by submitting a request to the addressee in paragraph (i)(1)(i) of this provision. Additional copies will be issued for a fee.
- (2) The DoD Index of Specifications and Standards (DoDISS) and documents listed in it may be obtained from the--

Department of Defense Single Stock Point (DoDSSP) Building 4, Section D 700 Robbins Avenue Philadelphia, PA 19111-5094

Telephone (215) 697-2667/2179 Facsimile (215) 697-1462.

FAR F 52.212-3 Offeror Representations and Certifications-Commercial Items (Continued6) (JUL 03)

(a) Definitions. As used in this provision:

"Emerging small business" means a small business concern whose size is no greater than 50 percent of the numerical size standard for the NAICS code designated.

"Forced or indentured child labor" means all work or service-

- (1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or
- (2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

"Service-disabled veteran-owned small business concern"-

- (1) Means a small business concern-
- (i) Not less than 51 percent of which is owned by one or more service-disabled Veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by

one or more service-disabled veterans or, in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern" means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and size standards in this solicitation.

"Veteran-owned small business concern" means a small business concern-

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101

(2) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and in the case of any publicly owned business, at least 51 percen

Offeror Representations and Certifications-Commercial Items Continued2 (JUN 03) FAR G 52.212-3 (2) The management and daily business operations of which are controlled by one or more veterans. "Women-owned business concern" means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women. "Women-owned small business concern" means a small business concern-(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and (2) Whose management and daily business operations are controlled by one or more women. (b) Taxpayer Identification Number (TIN) (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to a central contractor registration database to be eligible for award.) (1) All offerors must submit the information required in paragraphs (b)(3) through 7701(c) and 3325(d), reporting requirements of (b)(5) of this provision to comply with debt collection requirements of 31 U.S.C. and implementing regulations issued by the Internal Revenue Service (IRS). 26 U.S.C. 6041, 6041A, and 6050M, (2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN. Offeror Representations and Certifications-Commercial Items Continued3 (JUN 03) **FAR H** 52.212-3 (3) Taxpayer Identification Number (TIN). TIN has been applied for. TIN is not required because: Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States; Offeror is an agency or instrumentality of a foreign government; Offeror is an agency or instrumentality of the Federal Government. (4) Type of organization. Sole proprietorship; Partnership; Corporate entity (not tax-exempt); Corporate entity (tax-exempt); Government entity (Federal, State, or local); Foreign government; International organization per 26 CFR 1.6049-4; Other (5) Common parent. Offeror is not owned or controlled by a common parent; Name and TIN of common parent: Name ___ (c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply. (1) Small business concern. The offeror represents as part of its offer that it o is, o

is not a small business concern.

	 (2) Veteran-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it o is, o is not a veteran-owned small business concern. (3) Service-disabled veteran-owned small business concern. [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.] The offeror represents as part of its offer that it o is, o is not a service-disabled v
AR I	52.212-3 Offeror Representations and Certifications-Commercial Items Continued4 (JUN 03)
	(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply. (1) Small business concern. The offeror represents as part of its offer that itis, is not a small business concern. (2) Veteran-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it is, is not a veteran-owned small business concern. (3) Service-disabled veteran-owned small business concern. [Complete only if the offeror represented itself as a veteran-owned small business concern. (4) Small disadvantaged business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, for general statistical purposes, that it is, is not a small disadvantaged business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it o is, o is not a women-owned small business concern in paragraph (c)(1) of this provision.] The offeror represents that it o is, o is not a women-owned small business concern. Note: Complete paragraphs (c)(6) and (c)(7) only if this solicitation is expected to exceed the simplified acquisition threshold. (6) Women-owned business concern (other than small business concern in paragraph (c)(1) of this provision.]
	The offeror represents that it is a women-owned business concern.
AR J	52.212-3 Offeror Representations and Certifications-Commercial Items Continued5 (JUN 03)
	(7) Tie bid priority for labor surplus area concerns. If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:
	(8) Small Business Size for the Small Business Competitiveness Demonstration Program and for the Targeted Industry Categories under the Small Business Competitiveness Demonstration Program. [Complete only if the offeror has represented itself to be a small business concern under the size standards for this solicitation.] (i) [Complete only for solicitations indicated in an addendum as being set-aside for emerging small businesses in one of the four designated industry groups (DIGs).] The offeror represents as part of its offer that it is, is not an emerging small business. (ii) [Complete only for solicitations indicated in an addendum as being for one of the targeted industry categories (TICs) or four designated industry groups (DIGs).] Offeror represents as follows:
	(A) Offeror's number of employees for the past 12 months (check the Employees column if size standard stated in the solicitation is expressed in terms of number of employees); or
	(B) Offeror's average annual gross revenue for the last 3 fiscal years (check the Average Annual Gross Number of Revenues column if size standard stated in the solicitation is expressed in terms of annual receipts).
FAR K	52.212-3 Offeror Representations and Certifications-Commercial Items Continued6 (JUN 03)
	(Check one of the following):
	Number of Employees
	50 or fewer \$1 million or less 51-100 \$1,000,001-\$2 million 101-250 \$2,000,001-\$3.5 million 251-500 \$3,500,001-\$5 million 501-750 \$5,000,001-\$10 million 751-1,000 \$10,000,001-\$17 million Over 1,000 Over \$17 million
	(9) [Complete only if the solicitation contains the clause at FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, or FAR 52.219-25, Small Disadvantaged Business Participation Program-Disadvantaged Status and Reporting, and the offeror desires a benefit based on its disadvantaged status.] (i) General. The offeror represents that either-
	A) It is, is not certified by the Small Business Administration as a small disadvantaged business concern and identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration (PRO-Net), and that no material change in disadvantaged ownership and control has occurred since its certification, and, where the concern is owned by one or more individuals claiming disadvantaged status, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); or
	(B) Ithas,has not submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantage business concern in accordance with 13 CFR 124, Subpar tB, and a decision on that application is

pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

AR L	52.212-3	Offeror Representations and Certifications-Commercial Items Continued7 (JUN 03)							
	represents, as representation the joint venture	Ventures under the Price Evaluation Adjustment for Small Disadvantaged Business Concerns. The offeror part of its offer, that it is a joint venture that complies with the requirements in 13 CFR 124.1002(f) and that the in paragraph (c)(9)(i) of this provision is accurate for the small disvantaged business concern that is participating in re. [The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint]							
	(10) HUBZone (c)(1) of this p	small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph ovision.] The offeror represents, as part of its offer, that-							
	HUBZone Sma control, princip	is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified all Business Concerns maintained by the Small Business Administration, and no material change in ownership and all office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in the 13 CFR part 126; and							
	(c)(10)(i) of thi [The offeror sh venture:	is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph is provision is accurate for the BZone small business concern or concerns that are participating in the joint venture. all enter the name or names of the HUBZone small business concern or concerns that are participating in the joint] Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy ne representation.							
	(d) Representa	ations required to implement provisions of Executive Order 11246-							
FAR M	52.212-3	Offeror Representations and Certifications-Commercial Items Continued8 (JUN 03)							
	(1) Previous c	ontracts and compliance. The offeror represents that-							
	(i) It has solicitation; an								
	(ii) It has	has not filed all required compliance reports.							
	(2) Affirmative	Action Compliance. The offeror represents that-							
	(i) It has developed and has on file, has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or								
	(ii) It has of the Secreta	not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations ry of Labor.							
	1352). (Applie its offer, the o appropriated f attempting to an officer or e	n Regarding Payments to Influence Federal Transactions (31 U.S.C. s only if the contract is expected to exceed \$100,000.) By submission of fferor certifies to the best of its knowledge and belief that no Federal unds have been paid or will be paid to any person for influencing or influence an officer or employee of any agency, a Member of Congress, mployee of Congress or an employee of a Member of Congress on his or connection with the award of any resultant contract.							
	(f) Buy Americ Regulation (F.	can Act Certificate. (Applies only if the clause at Federal Acquisition AR) 52.225-1, Buy American Act-Supplies, is included in this solicitation.)							
	that the offero	r certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product and or has considered components of unknown origin to have been mined, produced, or manufactured outside the United fferor shall list as foreign end products those end products manufactured in the United States that do not qualify as products. The terms "component," "domestic end product," "end product,							
FAR N	52.212-3	Offeror Representations and Certifications-Commercial Items Continued9 (JUN 03)							
	(2) Foreign E	nd Products:							
	Line Item N	o. Country of Origin							
	[List as neces								
	• •	(3) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.							
	52 225-3 Buy	nerican Act-North American Free Trade Agreement-Israeli Trade Act Certificate. (Applies only if the clause at FAR y American Act-North American Free Trade Agreement-Israeli Trade Act, is included in this solicitation.) certifies that each end product, except those listed in paragraph (a)(1)(ii) or (a)(1)(iii) of this provision, is a domestic end							

	"component," "domestic solicitation entitled "Buy (ii) The offeror certifies t this solicitation entitled " NAFTA Country or Israe	of unknown origin to have end product," "end product," Mend product," and product," have a considered and product	e been mined, produced, or manufactured outside the United States. The terms uct," "foreign end product," and "United States" are defined in the clause of this erican Free Trade Agreement-Israeli Trade Act." are NAFTA country end products or Israeli end products as defined in the clause of American Free Trade Agreement-Israeli Trade Act":
	[List as necessary]		
	as defined in the clause	of this solicitation entitled	reign end products (other than those listed in paragraph (g)(1)(ii) of this provision) I "Buy American Act-North American Free Trade Agreement-Israeli Trade Act." The se end products manufactured in the Unit
FAR O	52.212-3 Offeror	Representations and C	ertifications-Commercial Items Continued10 (JUN 03)
	Other Foreign End Proc Line Item No.	ducts: Country of Origin	
	[List as necessary]		
	(iv) The Government wil	I evaluate offers in accord	lance with the policies and procedures of FAR Part 25.
			e Agreements-Israeli Trade Act Certificate, Alternate I (May 2002). If Alternate I to icitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the
	(g)(1)(ii) The offeror ceri efined in the clause of the Trade Agreement-Israel Canadian End Products Line Item No.	his solicitation entitled "Bเ i Trade Act":	oplies are Canadian end products as ny American Act-North American Free
	[List as necessary]		
	(3) Buy American Act-N		e Agreements-Israeli Trade Act Certificate, Alternate II (May 2002). If Alternate II to icitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the
	Israeli end products as	tifies that the following su defined in the clause of the Trade Agreement-Israe	oplies are Canadian end products or is solicitation entitled "Buy American li Trade Act":
	Canadian or Israeli End Line Item No.	Products: Country of Origin	
			<u></u>
	[List as necessary]		
FAR P		•	Certifications-Commercial Items Continued 11 (JUN 03) the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)
	(i) The offeror certifies t country, Caribbean Bas Agreements."	hat each end product, exc in country, or AFTA cou	cept those listed in paragraph (g)(4)(ii) of this provision, is a U.Smade, designated intry end product, as defined in the clause of this solicitation entitled "Trade"
	(ii) The offeror shall list country, or NAFTA cour		se end products that are not U.Smade, designated country, Caribbean Basin
	Other End Products:		
	Line Item No.	Country of Origin	
			<u>_</u>

	[List as necessary]
	(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items subject to the Trade Agreements Act, the Government will evaluate offers of U.Smade, designated country, Caribbean Basin country, or NAFTA country end products without regard to the restrictions of the Buy American Act. The Government will consider for award only offers of U.Smade, designated country, Caribbean Basin country, or NAFTA country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.
	(h) Certification Regarding Debarment, Suspension or Ineligibility for Award (Executive Order 12549). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals-
FAR P.1	52.212-3 Offeror Representations and Certifications-Commercial Item Continued 11.1 (JUN 03)
	(1) Are, are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency; and
	(2) Have, have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and
	(3) Are, are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses.
FAR P.2	52.212-3 Offeror Representations and Certifications-Commercial Item Continued 11.2 (JUN 03)
	(i) Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).]
	(1) Listed end products.
	Listed End Product Listed Countries of Origin
	
	(2) Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]
•	[] (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.
	[] (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.
FAR e	52.212-2 EvaluationCommercial Items (Jan 1999) (JAN 99)
	(a) The Government will award a contract resulting from this solicitation to the responsible offeror whose offer, conforming to the solicitation, will be most advantageous to the Government, price and other factors considered. The following factors shall be used to evaluate offers:
	Price and Past Performance. As part of their offer, the offeror is to detail their past performance in regard to efforts similar to that proposed for this award. Such performance may be with the key researcher's current organization/affiliation, or with any prior firm/organization. A point-of-contact and phone number should be provided for each distinct study or effort detailed. The offeror's Past Performance will be assessed for similarity to the proposed effort, based on the following parameters:
	a. Annual Dollar Value b. Length of Contract c. Shall have demonstrated performance in using single-chemical dose-response data to predict the expected dose-additive response of mixtures of those chemicals at specified total dose levels and specified relative proportions of the chemicals in the mixture. The definition of dose additivity shall be the same as that used by Berenbaum (Pharmacological Reviews, Vol. 1989, 41:93-141), as described by the interaction index: da/Da + db/Db + dj/Dj = 1, where da, db and dj are isoeffective and Da, Db and Dj are the concentrations in the mixture. Performance shall be demonstrated by publication in the peer-reviewed scientific literature. d. Shall have demonstrated the performance to incorporate biological variability in the estimate of the predicted mixture response by calculation of 95% prediction intervals for the predicted response of the mixture. Performance of such shall be demonstrated by publication in the peer-reviewed scientific literature. CLAUSE CONTINUED ON RFQ PAGE 1.

STATEMENT OF WORK.

DESCRIPTION OF PROJECT

The contractor shall analyze a data set comprised of 18 single chemicals and a fixed-ratio ray mixture of these 18 chemicals. The single chemicals include 2 dioxins, 4 dibenzofurans and 12 polychlorinated biphenyls. Each single chemical was evaluated at a minimum of 7 and a maximum of 9 dose levels. The mixture was tested at 6 non-zero dose levels. The endpoint of interest is serum thyroxine (T4) in animals dosed for 4 consecutive days. T4 was measured 24 hr after the last dose.

The data to be analyzed under this contract are the serum T4 data from this large project. As part of the scope of work of the contract, the contractor shall determine the suitability of the data for analysis by these methods.

The data shall be analyzed by the additivity models described in Gennings et al., 1997 (An Efficient Approach for Detecting Departure from Additivity in Mixtures of Many Chemicals with a Threshold Additivity Model, Journal of Agricultural, Biological and Environmental Statistics, 2:198-211, 1997), Gennings et al., 2002 (Statistical Analysis of Interactive Cytotoxicity in Human Epidermal Keratinocytes Following Exposure to a Mixture of Four Metals, Journal of Agricultural, Biological and Environmental Statistics, 7:58-73, 2002), Meadows et al. 2002 (Experimental Designs for Mixtures of Chemicals Along Fixed Ratio Rays, Environmental Health Perspectives, 110:979-983, 2002), Meadows et al. 2003 (Analysis of Mixtures of Drugs/Chemicals Along a Fixed Ratio Ray Without Single Chemical Data to Support an Additivity Model. Journal of Agricultural, Biological and Environmental Statistics, accepted subject to revision, 2003) and Gennings et al, 2003 (Analysis of Functional Effects of a Mixture of Five Pesticides Using a Ray Design, *Pharmacology and Toxicology*, Submitted, 2003). Specifically, the single-chemical data will be used, under an assumption of dose-additivity, to predict the response of the fixed-ratio mixture. By comparison of the predicted to the experimental data, an overall test of additivity will be provided as well as comparisons of the individual mixture points (predicted to observed). Individual data point predictions will include both the predicted value and the 95% prediction interval for the estimate.

PURPOSE

The purpose of this contract is to provide professional services for statistical analysis of a large mixture data set generated by the NHEERL/U.S. EPA. The contractor shall analyze and report the results of the data analyses to the U.S. EPA. Additivity model methods and techniques are to be used by the contractor. Such methods and techniques have been described by Gennings et al., 1997, Gennings et al., 2002 and Gennings et al, 2003. It is important that the data analysis for this data set be done based on methods and procedures suited to the experimental design used.

SPECIFIC TASKS IN THE STATEMENT OF WORK

- 1) Within one month of receipt of the data, the contractor shall develop a draft work plan for data analysis.
- 2) The contractor shall determine and provide summary statistics of the data at the beginning and end of the project (see Quality Assurance/Quality Control below). The summary statistics shall include, for each dose group, the mean serum T4, n (number of animals in the group) and SD (standard deviation).
- 3) The contractor shall evaluate the data supplied by the U.S. EPA to determine suitability for analysis by the specified techniques. If the serum T4 endpoint is determined not to be amenable to analysis by these methods, the contractor shall a) include the reasons as part of the final report and b) evaluate the suitability of other statistical analysis methods. The contractor shall also include suggestions for additional analyses of the data, including a preliminary determination of the suitability of analysis of the mixture data only by the Single Agent Not Required Method (Meadows et al., 2002, 2003; Gennings et al., 2003).
- 4) The contractor shall analyze the data set to determine the main effects of the 18 single chemicals.
- 5) The contractor shall analyze the data set to determine the interactive effects of the chemicals given in combination, based on comparison of the experimentally observed effect of the mixture on serum T4 to that predicted under an assumption of dose addition. By comparison of the predicted to the experimental data, an overall test of additivity will be provided as well as comparisons of the individual mixture points (predicted to observed). Individual data point predictions will include both the predicted value and the 95% prediction interval for the estimate. Following this analysis, the contractor may elect, based on the professional judgement of the contractor, to examine the data by other advanced statistical techniques.
- 6) If under Specific Task 4 a nonadditve interaction is detected, the contractor shall evaluate the suitability of the data for estimation of the interaction threshold. If the data are suitable, the estimated interaction threshold shall be determined.
- 7) The contractor shall prepare a final summary of the results of the above Specific Tasks and shall transmit the results to the U.S. EPA by means of both a written report and by oral communication of the results to the U.S. EPA. The written report shall be supplied to the U.S. EPA no later than two weeks prior to the oral communication of the results. The contractor shall visit the NHEERL/U.S. EPA for oral communication of the analysis results.

DELIVERABLES

There shall be three deliverables for this project.

- 1). A data analysis work plan to be developed upon receipt of the data. The draft work plan is due to the U.S. EPA within 2 working months of data receipt. The work plan should include the summary statistics requested under Specific Task 2.
- 2). An interim report providing progress to date. The interim report shall be due no later than 3

months after approval of the work plan by the U.S. EPA. At a minimum, the interim report shall provide the results of Specific Tasks 3 (suitability for analysis by specified techniques) and 4 (analysis of the single chemical data).

3). A final written report (Specific Task 7) conveying the results of the complete data analysis, including the results of each Specific Task, with emphasis on Specific Tasks 5 and 6. This will be followed by oral communication of the results to the U.S. EPA. The final report shall include the second set of summary data statistics (mean, n, SD) as specified under Quality Assurance/Quality Control.

US GOVERNMENT RESPONSIBILITIES.

- 1) The data set will be supplied to the contractor by the U.S. EPA.
- 2) The data will be entered in either SAS files or EXCEL files by U.S. EPA personnel.
- 3) The data files, along with a description of the code names used, will be sent to the contractor by e-mail.
- 4) The U.S.EPA will review the summary statistics to ensure that the group statistics provided by the contractor match those of the data set sent by the U.S. EPA to the contractor.
- 5) The U.S. EPA will establish a conference call with the contractor, once the data have been received, to answer any questions that the contractor may have regarding the data and the format in which they were transmitted.
- 6) The. U.S. EPA shall review the work plan and either approve it or recommend modifications. If modifications to the work plan are recommended, the U.S. EPA shall review and approve the modified work plan.
- 7) The U.S. EPA shall review and approve the interim report. If modifications to the interim report are suggested, the U.S. EPA shall review and approve the modified report.
- 8) The U.S. EPA shall review the final report and either accept it or recommend modifications. If modifications are recommended, the U.S. EPA shall review and approve the modified final report.
- 9) Upon receipt of the approved final report, the U.S. EPA shall establish a mutually agreeable date for the contractor to travel to NHEERL/U.S. EPA, RTP, NC for a verbal presentation of the final report.

QUALITY ASSURANCE/QUALITY CONTROL

Within 60 days of receipt of the data, the contractor shall provide summary statistics for each endpoint in the data set. These summary statistics are to consist of: a) the mean of the data; b) n (the number of observations in the data set); and, c) the standard deviation of the data. The U.S. EPA will compare these numbers to those generated by the U.S. EPA to ensure a) that the contractor received the proper data set, b) that errors did not occur during the transmission of the data and c) that the contractor is using the correct data in the subsequent analyses of the data. As

Statement of Work Continued

part of the final report, the contractor shall include a second set of summary statistics for each endpoint analyzed. This set of summary statistics shall provide the same information included in the first set of summary statistics, with the difference being that these shall be generated with the data used in the final statistical analysis of that endpoint. The contractor shall compare the first and second set of summary statistics and report any deviations to the U.S. EPA as part of the final report. Upon receipt of the final report, the U.S. EPA shall compare the three sets of summary statistics (the one generated by the U.S. EPA at the time the data are sent, the one generated by the contractor at the time the data are received and the one generated by the contractor for the data used in the final analysis of each endpoint).